

NIH NEWS

National Institute of Allergy and Infectious Diseases National Institutes of Health

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NIAID SEEKS APPLICANTS TO LEAD CLINICAL TRIALS UNITS FOR REVAMPED HIV/AIDS NETWORKS

The National Institute of Allergy and Infectious Diseases (NIAID) today announced that it is soliciting applications from U.S. and overseas research institutions seeking to become Clinical Trials Units (CTUs) in the Institute's revamped HIV/AIDS Clinical Trials Networks. NIAID, part of the U.S. National Institutes of Health (NIH), supports the world's largest portfolio of clinical research in HIV/AIDS prevention, vaccine and treatment research and development.

This solicitation, the second of two Requests for Applications (RFAs), is designed to increase the efficiency, accountability and integration of NIAID's HIV/AIDS clinical research networks and enhance their capacity to effectively conduct vital clinical research, especially in resource-limited settings.

The first solicitation, "Leadership for HIV/AIDS Clinical Trials Networks," was released in November 2004. The networks emerging from that RFA will focus on developing and evaluating treatments, prevention strategies and vaccines, with an emphasis on interventions that can be employed in resource-limited settings. The Clinical Trials Units funded in response to this RFA will carry out the research agendas of those networks in one or more of the following six priority areas of investigation:

- Developing HIV vaccines
- Translating research insights into therapies to treat HIV disease
- Optimizing clinical management of HIV/AIDS, including co-infections and other HIV-related conditions
- Developing microbicides to prevent HIV acquisition and/or transmission
- Preventing mother-to-child transmission of HIV
- Developing other methods of HIV prevention

"These Clinical Trials Units will help coordinate and carry out the next generation of AIDS research in the United States and globally," says NIAID Director Anthony S. Fauci, M.D. "Our goal is to develop the best possible leadership and research infrastructure to carry out a flexible, collaborative and coordinated approach to HIV vaccine, prevention and treatment research."

Funding for both the Network Leadership and the Clinical Trials Units is expected to total up to \$300 million for the first year and may continue for up to seven years. The earliest anticipated award date for the Leadership RFA is March 2006; Clinical Trials Units RFA awards are estimated to be made in mid- to late 2006.

Each Clinical Trials Unit will be led by a principal investigator and will comprise an administrative component and one or more clinical research sites. NIAID strongly encourages the establishment of CTUs that reach populations most affected or threatened by the HIV/AIDS epidemic in the United States and abroad, especially women, adolescents and people of color.

"The success of the restructured HIV/AIDS clinical networks will require the commitment of diverse institutions, an unprecedented degree of collaboration, and the involvement and support of communities affected by HIV/AIDS in the United States and around the world," notes Dr. Fauci.

The updated clinical research structure envisioned in the two RFAs emerged through extensive consultations with researchers, clinicians, nurses, community leaders, advocates and people living with and at risk for HIV/AIDS.

Application Information

Any public or private institution or organization, governmental or non-governmental, for-profit or nonprofit, can submit an application in response to the Clinical Trials Units RFA. These organizations, which can be domestic or foreign, may include universities, colleges, hospitals, private and group medical practices, units of state and local government, eligible agencies of the U.S. federal government and non-governmental agencies.

Four pre-application meetings devoted to a comprehensive overview of application submission requirements for the Clinical Trials Units RFA will take place at venues in the United States and abroad. The first day of each meeting will consist of a grant-writing workshop designed to build an understanding of the NIH grant application process and provide information on how to develop a grant application. The second day will feature an overview of application requirements, procedures and the review process. Meetings will be held in the following cities:

- Bethesda, MD (March 7-8, 2005)
- Miami, FL (March 17-18, 2005)
- Johannesburg, South Africa (March 31-April 1, 2005)
- Bangkok, Thailand (April 20-21, 2005)

Copies of the RFA for Clinical Trials Units for HIV/AIDS Clinical Trials Networks and information on the locations, logistics and other details of the pre-application meetings can be obtained at <http://www.niaid.nih.gov/daids/rfa/network06>.

NIAID is a component of the National Institutes of Health, an agency of the U.S. Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies.

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